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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,564	10/23/2003	Ohkmae Kim	P69208US0	2382
136	7590	08/29/2005	EXAMINER	
JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			COLLINS, CYNTHIA E	
		ART UNIT	PAPER NUMBER	
			1638	

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,564	KIM ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 July 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-12 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0104</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of SEQ ID No. 1 encoding the polypeptide of SEQ ID No. 2 in the reply filed on July 28, 2005 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, and claim dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite in the recitation of "the activity of an annexin". It is unclear what specific activity is referred to, as annexins are known to exhibit more than one type of activity, and the nature of the activity cannot be determined from the elements recited in the claim.

Claim 1, and claim dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite in the recitation of "the biological activity". There is insufficient antecedent basis for this limitation in the claim.

Claim 1, and claim dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. Claim 1 is indefinite in the recitation of “stringent conditions”. It is unclear what conditions would yield the claimed nucleic acid molecules, because those skilled in the art define “stringent conditions” differently. It is suggested that the claims be amended to recite specific hybridization conditions.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 is indefinite in the recitation of “related to”. It is unclear in what way the annexin is “related to” osmotic stress and ABA signaling, as a polypeptide may “related to” osmotic stress and ABA signaling in numerous ways (e.g. expression of the gene encoding the polypeptide may be increased or decreased in response to osmotic stress and ABA signaling, the polypeptide may be activated by osmotic stress and ABA signaling, the polypeptide may cause osmotic stress and ABA signaling, etc.), and the nature of the relationship cannot be determined from the elements recited in the claim.

Claim 6, and claim dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 is indefinite in the recitation of “vectors”. There is insufficient antecedent basis for “vectors” in claim 5 from which claim 6 depends.

Claim 9, and claim dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 is indefinite in the recitation of “the reduction of the polypeptide”. There is insufficient antecedent basis for this limitation in the claim.

Claim 9, and claim dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 is indefinite in the recitation of “an antisense”. It is unclear what “an antisense” refers to, as “antisense” is an adjective, but does not appear to modify a noun.

Claim 10, and claim dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 is indefinite in the recitation of “the increase of the polypeptide”. There is insufficient antecedent basis for this limitation in the claim.

Claim 10, and claim dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 is indefinite in the recitation of “a

sense". It is unclear what "a sense" refers to, as "sense" is an adjective, but does not appear to modify a noun.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 is indefinite in the recitation of "decreased", as "decreased" is a relative term that lacks a comparative basis.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 is indefinite in the recitation of "increased", as "increased" is a relative term that lacks a comparative basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark G.B. et al. I (GenBank ACCESSION AF083913, 02-JUN-1999 *Arabidopsis thaliana* annexin (AnnAt1) mRNA, complete cds., and Isolation and Characterization of Two Different *Arabidopsis* Annexin

cDNAs (Accession Nos. AF083913 and AF083914) (PGR 99-065) Plant Physiol. 120 (1), 340 (1999)).

The claims are drawn to an isolated nucleic acid molecule encoding a protein with the activity of an annexin or encoding a fragment of such a protein with the biological activity, which is selected from the group consisting of: (a) nucleic acid molecules encoding a polypeptide with the amino acid sequence of SEQ ID NO: 2; (b) nucleic acid molecules comprising the coding region of the nucleotide sequence of SEQ ID NO: 1; (c) nucleic acid molecules that hybridize under stringent conditions to nucleic acid molecules of (a) or (b); and (d) nucleic acid molecules that are degenerate to the nucleic acid molecules of any one of (a), (b), or (c). The claims are also drawn to a vector and a host cell.

Clark G.B. et al. teach an isolated nucleic acid molecule encoding a polypeptide with the amino acid sequence of SEQ ID NO: 2 and comprising the coding region of the nucleotide sequence of SEQ ID NO: 1, and a vector and host cell.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gidrol X. et al. I (GenBank ACCESSION U28415 *Arabidopsis thaliana* annexin-like protein mRNA, complete cds. 21-OCT-1996).

The claims are drawn to an isolated nucleic acid molecule encoding a protein with the activity of an annexin or encoding a fragment of such a protein with the biological activity, which is selected from the group consisting of: (a) nucleic acid molecules encoding a polypeptide with the amino acid sequence of SEQ ID NO: 2; (b) nucleic acid molecules comprising the coding region of the nucleotide sequence of SEQ ID NO: 1; (c) nucleic acid

molecules that hybridize under stringent conditions to nucleic acid molecules of (a) or (b); and (d) nucleic acid molecules that are degenerate to the nucleic acid molecules of any one of (a), (b), or (c). The claims are also drawn to a vector and a host cell.

Gidrol X. et al. I teach an isolated nucleic acid molecule encoding an annexin protein obtained from *Arabidopsis*, and a vector and host cell. The isolated nucleic acid molecule taught by Gidrol X. et al. I would hybridize under stringent conditions to nucleic acid molecules of (a) or (b), since the isolated nucleic acid molecule taught by Gidrol X. et al. I has 98.9% sequence identity with SEQ ID NO:1 (see attached sequence alignment).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark G.B. et al. I (GenBank ACCESSION AF083913, 02-JUN-1999 *Arabidopsis thaliana* annexin (AnnAt1) mRNA, complete cds., and Isolation and Characterization of Two Different *Arabidopsis* Annexin cDNAs (Accession Nos. AF083913 and AF083914) (PGR 99-065) Plant Physiol. 120 (1), 340 (1999)), Clark G.B. et al. II (Differential expression of members of the annexin multigene family in *Arabidopsis*. Plant Physiol. 2001 Jul;126(3):1072-84), Gidrol X. et

al. I (GenBank ACCESSION U28415 *Arabidopsis thaliana* annexin-like protein mRNA, complete cds. 21-OCT-1996) Gidrol X. et al. II (Annexin-like protein from *Arabidopsis thaliana* rescues delta oxyR mutant of *Escherichia coli* from H₂O₂ stress. Proc Natl Acad Sci U S A. 1996 Oct 1;93(20):11268-73) in view of Winicov I.I. et al. (Transgenic overexpression of the transcription factor alfin1 enhances expression of the endogenous MsPRP2 gene in alfalfa and improves salinity tolerance of the plants. Plant Physiol. 1999 Jun;120(2):473-80).

The claims are drawn to a plant transformed with an isolated nucleic acid molecule encoding a protein with the activity of an annexin or encoding a fragment of such a protein with the biological activity, which is selected from the group consisting of: (a) nucleic acid molecules encoding a polypeptide with the amino acid sequence of SEQ ID NO: 2; (b) nucleic acid molecules comprising the coding region of the nucleotide sequence of SEQ ID NO: 1; (c) nucleic acid molecules that hybridize under stringent conditions to nucleic acid molecules of (a) or (b); and (d) nucleic acid molecules that are degenerate to the nucleic acid molecules of any one of (a), (b), or (c), wherein said plant displays a decreased resistance to environmental stress as a consequence of expression of an antisense annexin polynucleotide, or an increased resistance to environmental stress as a consequence of expression of an sense annexin polynucleotide.

The teachings of Clark G.B. et al. I and Gidrol X. et al. I are set forth above.

Clark G.B. et al. I and Gidrol X. et al. I do not teach a transgenic plant that displays a decreased resistance to environmental stress as a consequence of expression of an antisense annexin polynucleotide, or a transgenic plant that displays an increased resistance to environmental stress as a consequence of expression of an sense annexin polynucleotide.

Gidrol X. et al. II teach that transformation of a delta oxyR mutant of *E. coli* with a vector comprising GenBank ACCESSION U28415 restored the ability of the delta oxyR mutant to grow in the presence of an environmental stress (H₂O₂) (page 11269 Figure 1). Gidrol X. et al. II also teach that oxidative stress is an important phenomenon in many biological systems, including plants, and that cellular damages produced by reactive oxygen species can lead to the development of a range of pathological symptoms (page 11268). Gidrol X. et al. II additionally teach that experimental evidence supports the hypothesis that annexins play a role in counteracting H₂O₂ stress in plants (page 11273).

Clark G.B. et al. II teach that the isolated nucleic acid molecule taught by Gidrol X. et al. I and Gidrol X. et al. II encodes the same type of annexin as the isolated nucleic acid molecule taught by Clark G.B. et al. I (page 1076 column 2 first full paragraph; page 1077 column 2 first full paragraph; page 1082 column 1 first paragraph).

Winicov I.I. et al. teach the expression of Alfin1, a putative transcription factor expressed in salt tolerant alfalfa plants, in transgenic alfalfa plants under the control of the 35S promoter in the sense and antisense orientations (page 474 Figure 1; page 477 Table II). Winicov I.I. et al. also teach that calli overexpressing Alfin1 were more resistant to growth inhibition by 171 mM NaCl than vector-transformed controls, whereas calli expressing Alfin1 in the antisense orientation were more sensitive to NaCl inhibition (page 476 Table I).

Given the teachings of Gidrol X. et al. II that annexins play a role in counteracting H₂O₂ stress in plants, and given the teachings of Winicov I.I. et al. that the function of a protein expressed in salt tolerant plants can be further evaluated by sense and antisense expression of its coding sequence in plant cells transformed therewith, it would have been *prima facie* obvious to

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one skilled in the art at the time the invention was made to express the annexin coding sequence taught by Clark G.B. et al. I or Gidrol X. et al. I in a sense and an antisense orientation in plant cells or plants transformed therewith. One skilled in the art would have been motivated to do so in order to evaluate the function of the annexin protein in plant cells or plants under H₂O₂ stress conditions. One skilled in the art would have had a reasonable expectation of success given the teachings of Gidrol X. et al. II that the encoded annexin protein restores the ability of the delta oxyR mutant of *E. coli* to grow in the presence of an environmental stress (H₂O₂). Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC

Cynthia Collins
8/24/05